OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

MAY 0 7 2003

MEMORANDUM FOR SURGEON GENERAL OF THE ARMY
SURGEON GENERAL OF THE NAVY
SURGEON GENERAL OF THE AIR FORCE

SUBJEC' Blood Donor Deferral for Severe Acute Respiratory Syndrome (SARS)

The U. S. Food and Drug Administration (FDA) issued Final Guidance for Industry, *Recommendations for the Assessment of Donor Suitability and Blood Product Safety in Cases of Suspected Severe Acute Respiratory Syndrome (SARS) or Exposure to SARS* on 17 April 2003 implementing blood donor deferrals for SARS. The Armed Services Blood Program Office has coordinated and is issuing Blood Program Letter (BPL) 03-06, Policy on Blood Donor Deferral for SARS.

This policy should be implemented no later than 18 May 2003. Details of this policy should be communicated to appropriate commanders, health care providers, and others involved in its implementation.

The point of contact for this matter is COL G. Michael Fitzpatrick, MS, USA, Director Armed Services Blood Program Office, at DSN 761-8024 or (703) 681-8024, glen.fitzpatrick@otsg.amedd.army.mil.

Ellen P. Embrey
Deputy Assistant Secretary of Defense
(Force Health Protection and Readiness)

DEPARTMENT OF DEFENSE
ARMED SERVICES BLOOD PROGRAM OFFICE
5109 LEESBURG PIKE
FALLS CHURCH, VA 22041-3258

REPLY TO
ATTENTION OF

ASBPO (40-2b)

BPL 03-06
9 May 2003

MEMORANDUM FOR SEE DISTRIBUTION

SUBJECT: Blood Donor Deferral for Severe Acute Respiratory Syndrome (SARS)

1. The Armed Services Blood Program Office (ASBPO) was established by the Assistant Secretary of Defense for Health Affairs to coordinate the blood programs of the Military Services and the Unified Commands. In that respect, the ASBPO is issuing Blood Program Letter (BPL) 03-06 notifying the Services to implement blood donor deferral for SARS consistent with U.S. Food and Drug Administration (FDA) guidance. Directions for implementation are contained in enclosure 1.

2. The Center for Disease Control and Prevention (CDC) and the World Health Organization continue to investigate a multi-country outbreak of an atypical pneumonia that is believed to be caused by a coronavirus. As of 30 April 2003, a total of 5,663 SARS cases have been reported from 26 countries (MMWR, Vol 52, No 17 (388-390), 2 May 2003). Though transmission of SARS by blood and blood product transfusion is yet unproven, the potential exists.

3. In an effort to mitigate the risk that SARS may be transmitted by transfusion, the FDA issued Final Guidance for Industry, (Recommendations for the Assessment of Donor Suitability and Blood Product Safety in Cases of Suspected Severe Acute Respiratory Syndrome (SARS) or Exposure to SARS) on 17 April 2003 (Enclosure 2). This guidance implements a 14 day deferral for persons who have traveled to a geographic area identified by the CDC as SARS affected, a 28 day deferral for persons who have had SARS or suspected SARS, and a 14 day deferral for persons who have had contact with patients who have had SARS or suspected SARS. This policy applies to collections of Whole Blood, blood components (including recovered plasma), Source Plasma and Source Leukocytes intended for use in transfusion or for further manufacture into injectable and non-injectable products. This policy is effective immediately and should be implemented as soon as feasible but no later than 18 May 2003.

4. **Service Blood Program Officers and Combatant Command Joint Blood Program Officers** must complete the enclosed form, *Acknowledgment of Receipt and Implementation*, (Enclosure 3) and return the signed original or fax copy to the ASBPO **NLT 16 May 2003.** A copy of all Service policy documents/letters implementing this BPL must also be forwarded to the ASBPO within 30 days of implementation. The ASBPO point of contact for this action is Lt Col Ruth Sylvester. She can be reached at DSN 761-8011/8024, commercial (703) 681-8011/8024, or via e-mail at ruth.sylvester@otsg.amedd.army.mil.

G. Michael Fitzpatrick

G. MICHAEL FITZPATRICK
COL, USA, MSC
Director

3 Enclosures
as stated

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Policy on Blood Donor Deferral for SARS

Purpose

Establish policy regarding blood donor deferral for Severe Acute Respiratory Syndrome (SARS). This policy applies to collections of Whole Blood, blood components (including recovered plasma), Source Plasma and Source Leukocytes collected from allogeneic and autologous donors intended either for use in transfusion or for further manufacture into injectable and non-injectable products. Services should update applicable Standardized Operating Procedures (SOP) in accordance with (IAW) this policy.

Background

SARS is an atypical pneumonia that is believed to be caused by a coronavirus. The Center for Disease Control and Prevention (CDC) and the World Health Organization continue to investigate this multi-country outbreak. As of 30April 2003, a total of 5,663 SARS cases have been reported from 26 countries (MMWR, Vol 52, No 17, 2 May 2003). CDC has defined the affected areas as mainland Mainland China; Hong Kong; Taiwan; Singapore; Hanoi, Vietnam; and Toronto, Canada. Though transmission of SARS by blood and blood product transfusion is yet unproven, the potential exists. Consequently, blood donor deferrals are being implemented to mitigate the risk of transfusion transmission of SARS.

Definitions

The following definitions apply to SARS in this policy:

Term	Definition
Suspected SARS	• Measured temperature >100.4 (>38^{o}C) **AND** • One or more clinical findings of respiratory illness (e.g. cough, shortness of breath, difficulty breathing, hypoxia, or radiographic findings of either pneumonia or acute respiratory distress syndrome), **AND** • Travel within 10 days of onset of symptoms to an area with current or recently documented community transmission of SARS (Attachment A). Travel includes transit in an airport with documented or suspected community transmission of SARS **OR**

Continued on next page

Definitions (continued)

Term	Definition

Suspected SARS (continued)	• Close contact within 10 days of onset of symptoms with a person:
	  • known or suspected to have SARS **OR**
	  • with a respiratory illness who traveled to a SARS-affected area
	
	• Additional information available on CDC website: http://www.cdc.gov/ncidod/sars/casedefinition.htm

Probable SARS	• Suspected SARS **AND** • Radiographic evidence of pneumonia or respiratory distress syndrome **OR** • Evidence of unexpected respiratory distress syndrome by autopsy
Close Contact	Having cared for, having lived with, or having had direct contact with respiratory secretions and/or body fluids of a patient known to be a suspected SARS case.

Donor Screening and Deferral

Perform the following 3 steps to determine if a donor is deferred for SARS:

Step	Action
1.	Provide each allogeneic and autologous donor with the SARS information sheet at Attachment B.
2.	Determine if the donor understood the information:

If the donor …	Then …
Understands the information	Continue
Does NOT understand the information	Explain and answer any questions for the donor

Continued on next page

Donor Screening and Deferral (continued)

Step	Action
3.	Determine if the donor is deferred for SARS IAW Service specific procedures:
	<table><tr><th>If the donor …</th><th>Then the donor is deferred for…</th></tr><tr><td>Had a history of SARS **OR** suspected SARS **OR** treatment for SARS</td><td>28 days from cessation of symptoms and/or treatment which ever is later NOTE: If donor is currently demonstrating symptoms, follow service specific infection control guidelines.</td></tr><tr><td>Had close contact with persons with SARS or suspected SARS and is *asymptomatic*</td><td>14 days after last exposure</td></tr><tr><td>Traveled to, transited through, or resided in areas affected by SARS (see Attachment A)</td><td>14 days from the date of arrival in the United States</td></tr></table>
4.	Document whether a donor is deferred for SARS IAW Service-specific procedures.
5.	Enter deferral in DBSS using DBSS Temporary Deferral Code 906

Post Donation Information and Lookback

Perform the following 7 steps for post donation information (PDI) related to SARS:

Step	Action
1.	Encourage donors to report any information listed below that becomes known to them after their donation: • Exposure to SARS within 14 days prior to their donation • Diagnosis of SARS within 28 days prior to donation • Development of SARS within 14 days after donation

Continued on next page

Post Donation Information and Lookback (continued)

<table>
<tr><th>Step</th><th>Action</th></tr>
<tr><td>2.</td><td>Identify and locate all products from the associated donation.</td></tr>
<tr><td></td><td>
<table>
<tr><th>If products are/were…</th><th>Then …</th></tr>
<tr><td>Available</td><td>Quarantine all products</td></tr>
<tr><td>Shipped</td><td>Notify consignee(s) to quarantine all products</td></tr>
</table>
</td></tr>
<tr><td></td><td>
<table>
<tr><th>If products are/were…</th><th>Then …</th></tr>
<tr><td>Transfused</td><td>Notify attending provider of potential transfusion SARS risk.</td></tr>
<tr><td>Destroyed</td><td>Document disposition.</td></tr>
</table>
</td></tr>
<tr><td>3.</td><td>Notify local public health of potential SARS donors and of any potential transfusion recipients IAW local procedures.</td></tr>
<tr><td>4.</td><td>Follow Service Directed protocols for shipment of quarantined products and/or patient samples for further study at CDC. Additional information on laboratory samples for CDC can be found at http://www.cdc.gov/ncidod/sars/lab.htm.</td></tr>
<tr><td></td><td>
<table>
<tr><th>If blood products are …</th><th>Then …</th></tr>
<tr><td>Needed for further testing</td><td>Ship IAW directions from Brooks AFB</td></tr>
<tr><td>NOT needed</td><td>Destroy IAW local policy</td></tr>
</table>
</td></tr>
<tr><td>5.</td><td>Document PDI and lookback if applicable IAW Service-specific SOPs.</td></tr>
<tr><td>6.</td><td>Enter donor deferral in DBSS using temporary deferral code 906</td></tr>
<tr><td>7.</td><td>Determine if Biologic Product Deviation (BPD) report is necessary.</td></tr>
<tr><td></td><td>
<table>
<tr><th>If a blood product was …</th><th>Then a BPD is …</th></tr>
<tr><td>Distributed</td><td>Required, contact Service Blood Program Office (SBPO)</td></tr>
<tr><td>NOT distributed</td><td>NOT required.</td></tr>
</table>
</td></tr>
</table>

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SARS Affected Areas

SARS affected areas

The following areas have been identified by the Center for Disease Control and Prevention as having documented or suspected community transmission of SARS:

Country
Mainland China (People's Republic of China)
Hong Kong
Singapore
Taiwan
Hanoi, Viet Nam
Toronto, Canada

Donor Information About SARS

What is SARS?

There is a growing epidemic of a new respiratory infection called SARS, short for Severe Acute Respiratory Syndrome. Most of the several thousand cases in the world have been identified in Asia, but some cases are being seen in the US and Canada as well as other countries.

How can I get SARS?

This infection is transmitted by direct contact with the respiratory secretions of people who have this infection. These are the droplets of liquid that are produced during coughing and sneezing. You will not get SARS from donating blood.

Can it be passed by blood transfusion?

There is no evidence it is transmitted from blood donors to transfusion recipients, but there is concern because the newly recognized virus associated with SARS is present in the blood of people who are sick. It is possible that the virus could be present in blood immediately before a person gets sick. This raises the issue of whether a blood donor with infection, but no symptoms, could transmit SARS by transfusion.

Can I donate blood today?

The Food and Drug Administration has recommended that people who have a risk of being infected with SARS not donate blood for a short interval. **You may not donate blood if you answer yes to any of the questions below:**

In the past 28 days, have you been ill with SARS or suspected SARS?
In the past 14 days, have you traveled to, traveled through or resided in any area affected by SARS? These areas are: **1. Mainland China (People's Republic of China)** **2. Hong Kong** **3. Singapore** **4. Taiwan** **5. Hanoi, Viet Nam** **6. Toronto, Canada**
In the past 14 days, have you cared for, lived with or had direct contact with body fluids of a person with SARS or suspected SARS?

After you donate

Please note that as long as you are and remain well, you need take no other measures. If you become ill with fever of 100.4 ^{o}F or higher, accompanied by a cough or trouble breathing, you should see your doctor. Remember that you should also call the blood center if you develop a fever and respiratory symptoms such as cough or trouble breathing in the 14 days after your donation. Thank you for helping to ensure the safety of the blood supply!

Guidance for Industry

Recommendations for the Assessment of Donor Suitability and Blood Product Safety in Cases of Suspected Severe Acute Respiratory Syndrome (SARS) or Exposure to SARS

FINAL GUIDANCE

This guidance is being distributed for immediate implementation.

FDA is issuing this guidance for immediate implementation in accordance with 21 CFR 10.115(g)(3). The agency has determined that seeking comments from the public prior to implementation is not appropriate since Severe Acute Respiratory Syndrome may pose immediate safety risks to the blood supply.

FDA invites comments on this document. Please submit comments to Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You should identify all comments with the docket number listed in the notice of availability that publishes in the Federal Register. FDA will review any comments received and will revise the guidance document as appropriate.

Additional copies of this guidance are available from the Office of Communication, Training, and Manufacturers Assistance (HFM-40), 1401 Rockville, MD 20852-1448, or by calling 1-800-835-4709 or (301) 827-1800, or from the Internet at http://www.fda.gov/cber/guidelines.htm.

For questions on the content of this guidance contact the Division of Blood Applications, Office of Blood Research and Review at (301) 827-3524.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research
April 2003

TABLE OF CONTENTS

Contains Nonbinding Recommendations

Guidance for Industry

Recommendations for the Assessment of Donor Suitability and Blood Product Safety in Cases of Suspected Severe Acute Respiratory Syndrome (SARS) or Exposure to SARS

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. INTRODUCTION

This guidance document provides our recommendations for assessing donor suitability and blood product safety with respect to Severe Acute Respiratory Syndrome (SARS). This guidance applies to Whole Blood and blood components intended for transfusion (including red blood cells for immunization) and blood components including recovered plasma, Source Leukocytes and Source Plasma intended for use in further manufacturing into injectable products or non-injectable products. Within this document, "donors" refers to all such donors. The Food and Drug Administration (FDA) developed the recommendations in this guidance in consultation with other Public Health Service Agencies of the Department of Health and Human Services. Within this guidance, "you" refers to blood establishments and "we" refers to the FDA. This guidance does not apply to tissue establishments or to human cells and tissues other than blood. However, tissue establishments may consider implementing similar donor screening practices.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

A. Epidemiology and Pathogenesis

The Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO) are investigating a worldwide outbreak of unexplained atypical pneumonia referred to as Severe Acute Respiratory Syndrome (SARS). As of 10 April 2003, over 2,500 suspected cases of SARS have been reported to WHO from nearly 20 countries; in the United

States, over 150 suspected cases (about 5% of cases worldwide) have been reported to CDC from about 30 states. Of the United States cases, about 95% had traveled to outbreak areas listed in the case definition within 10 days prior to the onset of clinical illness, and the remainder had a history of close contact with a person with suspected SARS. Of these cases reported worldwide, approximately 3.5 % (over 100 cases) have been fatal. In the United States, the majority of patients have recovered or stabilized clinically without specific antiviral therapy; no fatalities have been reported as of 10 April 2003 (Refs. 1-4 and unpublished CDC communication).

Laboratories at CDC and elsewhere (SARS Laboratory Network organized by WHO) have detected a new coronavirus in SARS patients (Refs. 5-9). Less often, a paramyxovirus (metapneumovirus) also has been found (Refs. 6, 7, 9). Both are lipid-enveloped, single-stranded RNA viruses. The identification of a novel coronavirus is consistent with a potential etiologic role, but the pathogenesis of SARS remains unclear at the present early stage of research. A co-factor role of paramyxovirus in this syndrome cannot be excluded. A diagnostic test for SARS based on the detection of acute infection with the novel coronavirus is currently under development (Refs. 5-9).

B. Definitions

1. CDC Case Definition of Suspected SARS

Until a diagnostic test is available, CDC's current interim case definition for a United States case of suspected SARS is as follows (Ref. 2):
Respiratory illness of unknown etiology with onset since 1 February 2003, which meets the following criteria:

- Measured temperature > 100.4 °F (>38 °C), AND
- One or more clinical findings of respiratory illness (e.g. cough, shortness of breath, difficulty breathing, hypoxia, or radiographic findings of either pneumonia or acute respiratory distress syndrome), AND
- Travel within 10 days of onset of symptoms to an area with documented or suspected community transmission of SARS (affected areas), OR close contact within 10 days of onset of symptoms with either a person with a respiratory illness who traveled to a SARS-affected area or a person known to be a suspect SARS case.
    - Please consult CDC for the updated list of affected areas (see section II.B.3 below for CDC website and phone number). The list is subject to change. (As of the publication date of this guidance, CDC has defined affected areas as: Peoples' Republic of China (i.e., mainland China and Hong Kong Special Administrative Region); Hanoi, Vietnam; and Singapore. The CDC definition excludes areas with secondary cases limited to healthcare workers or direct household contacts (as is the case at this time in Canada and the United States).)
    - Travel includes transit in an airport in an area with documented or suspected community transmission of SARS.

- Close contact is defined as having cared for, having lived with, or having had direct contact with respiratory secretions and/or body fluids of a patient known to be a suspect SARS case. Please consult CDC for the updated case definitions, including the definition of close contact (see section II.B.3 below for CDC website and phone number).

NOTE: Suspect cases with either radiographic evidence of pneumonia or respiratory distress syndrome or evidence of unexplained respiratory distress syndrome by autopsy are designated as "probable" cases of SARS according to the current WHO case definition (Ref. 4).

2. Use of CDC Case Definition in Guidance

For donor screening purposes, this guidance currently does not distinguish suspected SARS from probable SARS. The phrase "SARS and suspected SARS" as used in this guidance reflects the current lack of an available confirmatory diagnostic test for SARS.

Although WHO and CDC currently use 10 days as the incubation period in their respective case definitions, 14 days may be more appropriate for donor screening as a conservative upper limit of the asymptomatic incubation period (time between exposure to the SARS agent and the onset of clinical symptoms), based on current available information (Ref. 6). This guidance makes recommendations using 14 days as the asymptomatic incubation period.

3. Updated Information on Case Definitions and Areas Affected by SARS

Epidemiologic and laboratory investigations about SARS are ongoing. The case definitions and the list of affected areas worldwide are updated periodically as new information becomes available. The case definitions and the updated list of geographic areas affected by SARS may be obtained at the CDC website or by calling CDC:

Website: http://www.cdc.gov/ncidod/sars/casedefinition.htm
Phone: (888) 246-2675; 8 am - 11 pm weekdays, 10 am - 8 pm weekends

4. Infection Control Guidelines about SARS

Based on clinical and epidemiological experience to date, CDC has developed interim infection control guidelines for use at healthcare and household settings by infection control practitioners and clinicians providing medical care for patients with suspected SARS, including guidelines for triage of potential SARS cases. These guidelines are available at the CDC websites (Refs. 10-12). We recommend that blood center personnel consult these guidelines frequently to keep abreast of evolving CDC recommendations.

C. Impact of SARS on Blood Safety

The potential for transmission of SARS through blood and blood products is not known. The possibility of a viremic period, before the onset of clinical symptoms and/or after symptom resolution, remains an important concern regarding blood safety. The new coronavirus that is the possible cause of SARS has been isolated from infected kidney, lung, and bronchoalveolar-lavage fluid (Ref. 8) but has not been isolated yet from blood or serum of an infected individual (Refs. 5-9), though data are limited. Detection by nucleic acid amplification of this new coronavirus in blood samples from persons acutely infected with SARS has been reported in a single patient (Ref. 9). Because, as in some other early viral infections, persons with SARS could potentially be viremic without symptoms, transfusion transmission of SARS may be possible. Therefore, until more information is known about the epidemiology and pathogenesis of SARS, we recommend, as a preventative measure, the implementation of blood donor deferral for at least 14 days after possible exposure to SARS. Additionally, in cases of suspected SARS, we recommend donor deferral for at least 28 days after symptom resolution and completion of therapy due to the present uncertainty about possible persistence of viremia and/or viral shedding in body fluids (Ref. 9).

At this time, we believe SARS is unlikely to be transmitted through products manufactured from plasma. Lipid-enveloped RNA virus(es), the putative agent(s), should be readily removed and/or inactivated during manufacturing of plasma derivatives (Refs. 13, 14). Licensed plasma derivatives undergo intentional viral clearance procedures that are validated to be effective against lipid-enveloped RNA viruses. These procedures include: filtration, heating, acidification, and detergent treatment. Based on any new scientific information about the safety of plasma derivatives, we intend to revise these recommendations as appropriate.

D. Impact of Guidance on Blood Availability

Currently available epidemiologic data suggest that the implementation of SARS screening as recommended in this guidance will reduce the number of available donors by 0.1 to 0.2% and no more than 0.4%. Our recommendations contained in this guidance reflect recent active consultation with CDC. The recommendations are intended to serve as interim guidance until new scientific information becomes available. We will monitor closely the impact of this guidance on the blood supply. Based on that impact assessment and any new scientific information about the potential risk of transfusion transmission of the infectious agent(s) causing SARS, we intend to revise these recommendations as appropriate.

III. RECOMMENDATIONS

Consistent with existing regulations and applicable guidance, donors must be in good health at the time of donation [21 CFR 640.3(b) and 21 CFR 640.63(b)(3)]. Standard procedures that are already in place should serve as an effective safeguard against the unusual donor who seeks to donate after the onset of clinical illness. The following recommendations apply primarily to the potentially infected person during the asymptomatic incubation period before the onset of clinical symptoms.

A. Donor Interview Questions

At donor interview, we recommend that you ask (orally or in writing) potential donors about:

1. History of SARS, suspected SARS, or treatment for SARS within the previous 28 days. For example, "In the past 28 days, have you been ill with SARS or suspected SARS?"

2. Close contact within the previous 14 days with persons with SARS or suspected SARS. For example, "In the past 14 days, have you cared for, lived with, or had direct contact with body fluids of a person with SARS or suspected SARS?"

3. Travel to or residence in areas affected by SARS within the previous 14 days. Blood collection establishments with existing capture questions (e.g., "Have you traveled outside the United States within the past year?") should review these questions to ensure that they are adequate to identify possible travel to CDC-defined SARS affected areas. Capture questions may be followed up with questions specific to travel to SARS affected areas as necessary.

   If adequate travel capture questions are not currently in use, we recommend that donors be asked a specific question about travel or residence in areas affected by SARS within the past 14 days. For example, "In the past 14 days, have you traveled to, traveled through, or resided in areas affected by SARS?"

   Note that you should read to or show donors a list of affected areas as updated by CDC. See below for CDC contact information

To ensure that the questions used remain consistent with updated case definitions and the list of geographic areas affected by SARS, we recommend that you routinely and periodically refer to the CDC website (www.cdc.gov/ncidod/sars/casedefinition.htm) or call CDC (888-246-2675; 8 am - 11 pm weekdays, 10 am - 8 pm weekends) to obtain the updated information.

B. Donor Deferral Actions

We recommend that donors reporting a history of SARS or suspected SARS be asked about duration of symptoms and any treatment given. We recommend that you defer these donors for a period of at least 28 days after complete symptom resolution AND the cessation of any treatment.

For asymptomatic donors with a history of contact with persons with SARS or suspected SARS, we recommend that you defer these donors for a period of at least 14 days after last exposure. For travel/residence exposure, the donor should be deferred for at least 14 days after arrival in the United States.

C. Post-Donation Information and Lookback Investigation

We recommend that you actively encourage donors to report, post donation, any further information about SARS exposure that may have occurred within 14 days prior to donation, or SARS illness or treatment within 28 days prior to donation. Donors should also be encouraged to report SARS illness or treatment that occurs within 14 days after donation. These recommendations on post-donation information and lookback investigation apply to Whole Blood and blood components intended for transfusion (including red blood cells for donor immunization), and to unpooled units of recovered plasma and Source Plasma, and Source Leukocytes, but not to pooled units of plasma.

1. Product Retrieval and Quarantine

If a donor reports, post donation, a history of SARS disease (as described in section III.A.1, above) that occurred within 28 days prior to blood collection, SARS exposure (as described in sections III.A.2 and III.A.3, above) that occurred within 14 days prior to blood collection, or SARS disease that occurred within 14 days after blood collection, we recommend that blood establishments promptly retrieve and/or quarantine the collected in-date units of Whole Blood and/or blood components and any unpooled units collected for further manufacturing.

NOTE: If the donor is symptom-free more than 14 days post-exposure, product retrieval and quarantine are not necessary.

2. Product Disposition and Special Labeling

Quarantined units should be destroyed in accordance with established procedures, unless distributed for further manufacturing into non-injectable products or for research use under special labeling, as follows:

"Biohazard," AND
"Collected from a donor with SARS exposure or suspected SARS,"

AND

"For laboratory research use only," OR
"Intended only for further manufacturing into non-injectable products."

3. Physician Notification about Potential Transfusion-Transmitted SARS

A blood establishment (including a blood collecting establishment or transfusion service) may receive information that a donor of already-transfused blood or blood components has been exposed to SARS, or became sick with suspected SARS, during the time frames described in section III.A.1-3. We recommend that the establishments consider notifying the treating physician of those recipients about the post donation information, including whether the donor developed suspected SARS.

4. Notification of State or Local Public Health Departments about Suspected Donor Cases of SARS

We recommend that blood establishments report cases of SARS in either donors or blood recipients to their respective state or local public health departments. Also, if a donor reports the existence of clinical symptoms consistent with SARS within 14 days subsequent to donation, and a possible SARS exposure, CDC has asked blood establishments to contact the CDC Division of Viral and Rickettsial Diseases, Assistant Director for Blood Safety (404-639-2775) to determine if retrieved units should be sent to CDC for laboratory studies, under quarantine and specially labeled as indicated above.

IV. BIOLOGIC PRODUCT DEVIATION AND FATALITY REPORTING

Regulations on reporting of product deviations by licensed manufacturers, unlicensed registered blood establishments, and transfusion services are located at 21 CFR 606.171 and 21 CFR 600.14. Pursuant to these regulations, blood and plasma collection establishments (including establishments that collect Source Leukocytes and licensed manufacturers of leukocyte derivatives) must submit biological product deviation reports for events related to SARS, if the establishment distributed the affected product. Additionally, if a suspect donation results in the fatality of a transfusion recipient, blood establishments must report the fatality to the FDA [21 CFR 606.170(b)].

V. IMPLEMENTATION

We recommend that you implement the recommendations in this guidance as soon as feasible, but not later than 30 days after the guidance issue date. Consistent with 21 CFR 601.12, licensed establishments implementing these recommendations should submit by official correspondence a statement in their annual reports indicating the date that the establishment revised and implemented their standard operating procedures, consistent with these recommendations. These changes do not require our prior approval.

VI. REFERENCES

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14. Bucknall RA, King LM, Kapikian AZ, et al. Studies with human coronaviruses. II. Some properties of strains 229E and OC43. Proceedings of the Society of Experimental Biology and Medicine 1972; 139:722-727.

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BPL 03-06

Policy on Blood Donor Deferral for SARS

9 May 2003

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